

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

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| To: Madderns 1st Floor Wolf Blass House 64 Hindmarsh Square ADELAIDE SA 5000 |
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

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| Applicant's or agent's file reference 29322PCT | | Date of mailing <i>(day/month/year)</i> <div style="float: right;">01 DEC 2006</div> |
| International application No. PCT/AU2006/001632 | | FOR FURTHER ACTION See paragraph 2 below |
| International filing date <i>(day/month/year)</i> 2 November 2006 | Priority date <i>(day/month/year)</i> 10 November 2005 | |
| International Patent Classification (IPC) or both national classification and IPC Int. Cl. A61F 2/18 (2006.01) A61F 11/00 (2006.01) | | |
| Applicant COCHLEAR LIMITED et al | | |

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43 <i>bis</i> .1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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|---|---|---|
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929 | Date of completion of this opinion 23 November 2006 | Authorized Officer G.M. COX Telephone No. (02) 6283 2178 |
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/001632

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material .
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed. .
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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International application No.

PCT/AU2006/001632

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|----------------------|------------|
| Novelty (N) | Claims | YES |
| | Claims 1 to 6 | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1 to 6 | NO |
| Industrial applicability (IA) | Claims 1 to 6 | YES |
| | Claims | NO |

2. Citations and explanations:

Novelty and Inventive Step: Claims 1 to 6

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: US 4986831 A (KING) 22 January 1991: Claims 1 and 2

D2: WO 2004014269 A (COCHLEAR LIMITED) 19 February 2004: Claims 1 to 6

D3: WO 2004014270 A (COCHLEAR LIMITED) 19 February 2004: Claims 1 to 6

D5: WO 2003092326 A (COCHLEAR LIMITED) 6 November 2003: Claims 1 to 6

D1 discloses a medical implant (21) which is anchored or tethered (29) to the wall of a blood vessel (43).

D2 discloses the fixing of a cochlear implant via flanges (39) which "extend outside the perimeter of the implanted receiver/stimulator unit (38)". The unit may also be conformable (see page 16 line 32 to 34). The housing may be detachable (see figures 13 and 14 and specification on page 15 lines 1 to 17). In addition the citation discloses arrangements (see figures 11 to 12) in which the distance between the fixation point and the medical implant is variable.

D3 discloses a fixation system for a cochlear implant. The fixation point comprises a flange (42) which extends outwardly from the housing (22). The flanges are conformable (see page 5 lines 16 and 17). The flanges are not fixedly attached to the unit (38)-see figure 6 and description on page 16 lines 8 to 14. In addition, the citation discloses the use of different screw sites for attachment (see page 15 lines 33 to 35) and so the concept of variability in the distance between the fixation point and the medical implant is disclosed.

D5 discloses an cochlear implant in which an anchor member (23) anchors the magnet (22) of the implantable receiver (12) to a part of the body of the recipient. The specification inherently discloses the features of conformability which can be inferred from the materials used. The distance of the fixation point being variable is also inferred from the description-see for example figure 6 in which different arrangements inherently disclose differing distances.

WRITTEN OPINION OF THE
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International application No.

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Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

| <u>Application No. Patent No.</u> | <u>Publication date (day/month/year)</u> | <u>Filing date (day/month/year)</u> | <u>Priority date (valid claim) (day/month/year)</u> |
|---------------------------------------|--|---|---|
| RU 2282426 | 27 AUGUST 2006 | 27 DECEMBER 2004 | 27 DECEMBER 2004 |

D4: DERWENT ABSTRACT ACCESSION NO. 2006-555721/57, CLASS P32 RU 2282426 A (MIKROB ANTI-PLAGUE RES INST) 27 August 2006

This document, from the abstract, discloses a method of fixing a cochlear implant on a cranium surface. The fixation points are grooves formed in the walls of the bone bed.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

| <u>Kind of non-written disclosure</u> | <u>Date of non-written disclosure (day/month/year)</u> | <u>Date of written disclosure referring to non-written disclosure (day/month/year)</u> |
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International Application No.

PCT/AU2006/001632

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

It is clear from the disclosures in the above documents that the essential features of the remoteness of the fixation point are disclosed and that the subject matter of dependent claims 2 to 6 is disclosed. Therefore the subject matter of these claims is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty. Consequently, the subject matter of these claims is also obvious and does not meet the requirements of Article 33(3) of the PCT with regard inventive step.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.